Re-evaluation Note REV2013-08

# Re-evaluation Project Plan for Fludioxonil

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In Canada, fludioxonil is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they continue to meet standards of modern science and current policy established to protect human health and the environment. Under the authority of Section 16 of the *Pest Control Products Act*, the registrant of fludioxonil was notified of the initiation of the re-evaluation of fludioxonil. Following this, the registrant of fludioxonil technical grade active ingredient in Canada indicated their intention to support all uses included on the labels of commercial class products in Canada. This Re-evaluation Note outlines a project plan and timeline for review, as well as summarizes the anticipated area of focus related to the re-evaluation of fludioxonil.

Fludioxonil is a protectant, contact fungicide that has been registered in Canada since 1996. Fludioxonil is currently registered as a seed treatment for a wide range of food and feed crops (Use-Site Category 10). Fludioxonil is also registered for the control or suppression of a number of foliar diseases on various terrestrial food crops (Use-Site Category 14), for industrial oil seed crops and fibre crops (Use-Site Category 7), greenhouse cucumbers (Use-Site Category 5), stored food crops (Use-Site Category 12), turf (Use-Site Category 30), and outdoor ornamentals (Use-Site Category 27). Registered fludioxonil end-use products are formulated as solutions or suspensions, wettable granules, dusts or powders, to be applied by ground or aerial equipment and by drench and dip applications for postharvest treatment and seed treatment.

The project plan discussed below outlines the anticipated area of focus and risk assessments required to complete the re-evaluation of fludioxonil. Should additional information become available during the re-evaluation period that affects the regulatory status of fludioxonil, the PMRA will reconsider the area of focus and risk assessments required. Currently, a proposed re-evaluation decision for fludioxonil is anticipated to be published in 2014.

## Re-evaluation Project Plan

### Human Health Risk Assessment

The toxicology database for fludioxonil is considered complete, and more recent approaches including consideration of the PCPA factor and toxicology endpoint verification have been addressed since its initial registration. Comprehensive assessments were conducted for worker applicator and postapplication exposures, as well as non-occupational assessments for aggregate, residential and bystander exposures during the initial registrations of the respective uses of fludioxonil. However, the quantitative risk assessments for the seed treatments will be reviewed and updated using contemporary methodologies and data.

### Environmental Risk Assessment

Environmental risk mitigation measures will be reviewed to ensure consistency with current label requirements and the Toxic Substances Management Policy will be considered.

### Value

The value of fludioxonil will be considered. The viability of alternatives will be examined if risks of concern are identified.

### Data Requirements

No additional data requirements have been identified for fludioxonil at this time.

### Anticipated Timeline for Re-evaluation

A proposed re-evaluation decision for fludioxonil is anticipated to be published for consultation in 2014.

## Additional Information

PMRA documents can be found in the Pesticides and Pest Management section of Health Canada's website at www.healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.